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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,292	03/29/2004	Dennis E. Discher	046483-5152-03-US (435585)	2280
23973 7590 07/23/2009 DRINKER BIDDLE & REATH ATTN: INTELLECTUAL PROPERTY GROUP ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996			EXAMINER SILVERMAN, ERIC E	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 07/23/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/812,292	<b>Applicant(s)</b> DISCHER ET AL.	
	<b>Examiner</b> ERIC E. SILVERMAN	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Piskin et al in view of Won et al. for reasons of record and those discussed below.

### ***Response to Arguments***

Applicants' arguments have been considered, but are unpersuasive.

Applicants argue that neither reference teaches the claimed appropriate blend ratio, because neither reference teaches blending the two components of the vesicle. In response, claim 1 is open to any blend ratio and does not define particular ratios as "appropriate". Because the claims are not limited to any particular blend ratios, patentability cannot be based on the blend ratios.

Applicants next argue that the PDLLA/PEG micelles of Piskin are made by transesterification, which requires a co-solvent. In response, Applicants' misunderstand the Piskin reference. Transesterification is not a process used to make the micelles, it is a process used to synthesize the PDLLA/PEG polymer itself. A chemist knows that transesterification means a reaction that replaces the alcohol part of an ester with a different alcohol part. For example, a methyl ester might undergo a transesterification reaction with ethanol to give an ethyl ester. This is not a process that makes micelles.

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Instant claims only require that no cosolvent be used in the process of making the micelles, and does not require that no cosolvent be used in the process of preparing the polymers that are then used to make micelles.

Applicants also argue that there is no motivation to combine the two references because while Piskin teaches classically sized micelles, Won's vesicles have a different size and are different viscoelastic properties. In response, Applicants have not provided any reason why the different sizes or viscoelastic properties would deter the artisan from the combination of Piskin and Won. The position of this office is that it would not because the polymers in Piskin and Won are both taught specifically for use in micelle formation. Nor have applicants offered any reason why the viscoelastic properties of Won would be undesirable in Piskin. On the contrary, the prior art notes advantages to the unique properties in Won, which the artisan would expect to be available in Piskin when the references are combined.

Applicants next argue that the references would not suggest that the claimed method would lead to vesicles having tunable release properties, and that such properties are unexpected. Applicants explain that Piskin and Won teach vesicles made of PDLLA/PEG and PEG-PBD, respectively. In Piskin and Won, the release of encapsulated material depends on the degradation of PDLLA/PEG (Piskin) or of PEG-PBD. Applicants note that in the instant method, the degradation rate depends on blending ratio which allows for customization of the degradation rate. Contrary to Applicants assertion, this is exactly the result that the artisan would expect.

Degradation of a polymer is a chemical reaction between the polymer and other

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molecules in its environment. The degradation rate of a polymer depends on the polymers chemical structure and molecular weight. The chemical structure determines how the polymer reacts with other molecules in its environment; for example, polyesters can be degraded by ester hydrolysis catalyzed by acid, base, or esterases. The molecular weight determines how many individual reactions are needed to break down the polymer; for example, to break down a polyester having 100 repeat units into its component monomers requires 99 hydrolysis, whereas to break down a polyester having 5 repeat units into its monomers requires 4. When two polymers that do not react are blended, the degradation rate of either polymer does not change. The degradation rate of the blend is approximated by the weighted average of the degradation rate of the components. For example, consider a blend contains polymers A and B, which have degradation rates  $D_a$  and  $D_b$ , respectively. Imagine that  $X_A$  and  $X_B$  are the mol fractions of A and B, respectively, in the blend, and  $D_{a/b}$  is the degradation rate of the blend. The degradation of the blend can be approximated by the equation:  $(X_A \cdot D_a) + (X_B \cdot D_b) = D_{a/b}$ . In this equation, if the mol fraction is based on the weight average molecular weight of the polymers then the weight fraction can be substituted for the mol fraction. Note that the above analysis is based completely on first principles, and is analogous to other systems that are well known to the chemist such as azeotropic distillation, or the surface tension of a homogeneous mixture of liquids.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/

Primary Examiner, Art Unit 1618